

## REMARKS

### **A. Status of the Claims**

By the present amendment, claims 67, 91, 95, 111, 129, and 130 have been amended to more particularly define the Applicant's invention and to claim it with greater specificity. Claims 70, 73, 112, and 113 have been canceled. Claims amendments are supported by the specification and the original claims. No new matter has been added.

After the proposed amendment has been entered, claims 67, 74-81, 84-91, 95-111, and 114-145 will be under consideration.

### **B. Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 67, 70, 73-81, 84-91, 101-103, 111-129, and 136-138 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subjected matter which the Applicant regards as the invention (see, page 2, third paragraph of the Office Action). The rejection is respectfully traversed.

The gist of the Examiner's rejection seems to be based on her observation that the claims are silent with regard to a possibility that the recited mitochondrial disorders may be either primary or secondary, and provides an excerpt from the Merck Manual to prove her point. The Examiner also seems to ask for clarification of causes of secondary disorders (see, the last paragraph on page 2 of the Office Action).

While the Applicant respectfully disagrees with the Examiner's rationale, in order to accelerate the prosecution of the instant application, claims 67, 91, 111, and 129 have been amended and all now specify that both primary and secondary disorders are within

the purview of the claims. In view of the amendment, claims 70, 73, 112, and 113 have become redundant and have been, consequently, canceled.

Accordingly, the rejection has become moot. In view of the foregoing, it is respectfully submitted that the rejection of claims 67, 70, 73-81, 84-91, 101-103, 111-129, and 136-138 under 35 U.S.C. § 112, second paragraph, does not apply. Reconsideration and withdrawal of the rejection are respectfully requested.

**C. Rejections Under 35 U.S.C. § 103 (a)**

Claims 67, 70, 73-81, 84-91, 96-109, and 111-179 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious Nagley in view of Page et al., "Developmental Disorder Associated with Increased Cellular Nucleotidase Activity," Proc. Natl. Acad. Sci. USA, vol. 94, pp. 11601-11606 (1997) ("Page")(page 4, last paragraph of the Office Action). The rejection is respectfully traversed.

With regard to claims 67, 74-81, 84-91, 96-109, 111, and 114-179, the Applicant's position remains that the KSR standard that has to be satisfied in order to make a valid rejection based on a *prima facie* case of obviousness has not in fact been satisfied as applied to these claims, as currently amended.

The Examiner's position seems to be that Nagley describes treatments directed to lactic acidosis and the therapy taking advantage of the mitochondrial effects of AZT, while Page teaches the safe and effective use of certain uridine dosing. Accordingly, the Examiner reading the instant claims broadly concluded that there is an expectation of success for treating mitochondrial disorders using the teachings of Nagley.

The Applicant respectfully disagrees that the Examiner brings teachings directed to multiple therapeutic agents into the process of interpreting the instant claims. While the use of unrelated agents such as AZT is not currently excluded, there is nothing in the application giving even a slightest indication as to the possibility of their use. Even

though the Applicant agrees that the Examiner is indeed allowed a broad latitude in reading claims, it is respectfully submitted that the Examiner has read claims too broadly. It is, of course, axiomatic that claims are interpreted in view of disclosure, and the current disclosure has nothing to do with AZT or other kinds of therapeutics.

For the above-stated reasons, the Applicant respectfully disagrees with the Examiner's rationale used in making the obviousness rejection. However, being desirous of facilitating the process of prosecution, the Applicants has amended claims 67, 91, 111, and 129. Each of these claims now has close language "consisted of" when reciting the therapeutic agents. Thus, reading these claims as broadly as the Examiner did is impossible.

Accordingly, teaching of Nagley describing the mitochondrial effects of AZT cannot be now used, because claims 67, 91, 111, and 129, as amended, exclude the use of AZT or any agents other than L or D isomer of a keto or a enol tautomer of Formula I, or IA. Therefore, the combination of Page and Nagley fails to satisfy one of the crucial requirements of *KSR*, i.e., fails to teach or suggest all of the limitations recited in claims 67, 91, 111, and 129, as amended.

In view of the foregoing, it is respectfully submitted that each of claims 67, 91, 111, and 129 is patentably distinguishable over Nagley in view of Page. Each of claims 74-81, 84-90, 96-109, 114-128, and 130-145 directly or indirectly depends on either claim 67, 91, 111, or 129, and is accordingly considered patentable for at least the same reason. As to claims 70, 73, 112, and 113, the rejection has become moot in view of the cancellation of these claims. Withdrawal of the rejection and reconsideration are respectfully requested.

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**D. Claims Objections**

The Examiner continues to object to claims 95-100, 104-110, 130-135, and 139-145, while conceding that these claims are directed solely to MARIAHS syndrome and are free of prior art. To obviate these objections, the Applicant has amended claims 95 and 130 and presented them in the independent form. It is submitted that there are no issues that remain to be resolved with respect to claims 95-100, 104-110, 130-135, and 139-145.

In view of the foregoing, withdrawal of the objection, reconsideration and allowance of claims 95-100, 104-110, 130-135, and 139-145 are requested.

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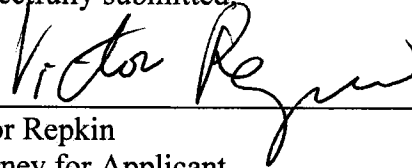
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**CONCLUSION**

In view of the above amendments and remarks, reconsideration and favorable action on all claims are respectfully requested. In the event any matters remain to be resolved, the Examiner is requested to contact the undersigned at the telephone number given below so that a prompt disposition of this application can be achieved.

No fee is deemed to be due in connection with this response. However, the Commissioner is hereby authorized to charge any other fees that may be due in connection with the filing of this paper, or credit any overpayment to Deposit Account No. 07-1896, referencing the above-referenced Attorney docket number.

Respectfully submitted,



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